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Registration Decision RD2011-01

Flonicamid

(publié aussi en français)

24 January 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: HH13-25/2011-IE (print version)
HH13-25/2011-IE-PDF (PDF version)

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Registration Decision for Flonicamid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and Regulations, is granting full registration for the sale and use of Flonicamid Technical Insecticide and Beleaf 50SG Insecticide, containing the technical grade active ingredient flonicamid, to control aphids on a variety of agricultural crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision PRD2010-25 *Flonicamid*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for flonicamid and summarizes the Agency's decision. The PMRA received no comments on PRD2010-25. This decision is consistent with the proposed registration decision stated in PRD2010-25.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-25 - *Flonicamid* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*" ...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Flonicamid?

Flonicamid is an insecticide that controls aphids by stopping them from feeding. This anti-feeding effect eventually results in the death of the insect. Aphids must come into contact or ingest flonicamid for it to be effective.

Health Considerations

Can Approved Uses of Flonicamid Affect Human Health?

Flonicamid is unlikely to affect your health when used according to label directions.

Potential exposure to flonicamid may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when flonicamid products are used according to label directions.

The technical grade active ingredient flonicamid is of moderate toxicity when administered as a single oral dose to rats; consequently, the hazard signal words "WARNING - POISON" are required on the label. It is of low acute toxicity when administered to rats dermally or through inhalation. Flonicamid is non-irritating to the eyes and minimally irritating to the skin of rabbits, and does not produce a skin sensitizing response in guinea pigs.

The acute toxicity of the end-use product Beleaf 50SG Insecticide is low via the oral, dermal and inhalation routes of exposure. It is non-irritating to the skin and is not considered a skin sensitizer. Beleaf 50SG Insecticide is mildly irritating to the eyes. Consequently, the hazard signal words "CAUTION – EYE IRRITANT" are required on the label.

Health effects in animals given daily doses of flonicamid over long periods of time included effects on the liver, kidney, spleen, bone marrow and lung. There was evidence of perturbations in reproductive hormones, however, there was no effect on the ability to reproduce. There was no indication that flonicamid caused damage to the nervous system, or evidence to suggest that flonicamid damaged genetic material. Flonicamid did, however, cause the formation of lung tumours in mice.

When flonicamid was given to pregnant animals, minor effects on the developing foetus were observed at doses that were toxic to the mother, indicating that the foetus is not more sensitive to flonicamid than the adult animal.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that children 1-2 years old, the subpopulation which would ingest the most flonicamid relative to body weight, are expected to be exposed to less than 7.3 % of the acceptable daily intake. Based on these estimates, the chronic dietary risk from flonicamid is not of concern for all population sub-groups.

A single dose of flonicamid is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act (FDA)* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA)*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using flonicamid on broccoli, cabbage, mustard greens, cantaloupe, cucumber, summer squash, tomato, pepper, celery, leaf lettuce, head lettuce, spinach, potato, radish, carrot, apple, pear, peach, cherry, plum, and hops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of PRD2010-25.

Risks in Residential and Other Non-Occupational Environments

Entry by the public into treated commercial areas is considered acceptable.

No risk assessment was required for adults and children entering treated commercial areas for 'pick-your-own' harvest activities as there were no effects in the toxicology database that warranted the establishment of an acute reference dose.

Occupational Risks From Handling Beleaf 50SG Insecticide

Occupational risks are not of concern when Beleaf 50SG Insecticide is used according to the label directions, which include protective measures.

Farmers and custom applicators that mix, load or apply Beleaf 50SG Insecticide, as well as field workers re-entering treated fields can come in direct contact with flonicamid residues on the skin, or by inhalation. Therefore, the label specifies that anyone mixing or loading Beleaf 50SG Insecticide must wear a long-sleeved-shirt, long pants, chemical-resistant gloves and goggles; and that anyone applying the product must wear a long sleeve shirt and long pants. The label also requires that workers do not enter treated fields or other treated sites for at least 12 hours after application, or longer, depending on the crop and tasks to be performed. Taking into consideration these label statements, the number of applications and the expected exposure period for handlers and workers, the risks to these individuals are determined not to be of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Flonicamid Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when Beleaf 50SG Insecticide is used according to label directions, which include precautionary label statements and buffer zones.

Flonicamid enters the environment when used as an insecticide on a variety of crops. Flonicamid is not persistent in soil and slightly to moderately persistent in water, while the environmentally relevant major transformation products, TFNA, TFNA-OH, TFNG, and TFNG-AM are not persistent in soil and moderately persistent in water. The transformation products rapidly mineralize in aerobic soil. Flonicamid and its major transformation products are mobile and expected to leach. However, based on rapid dissipation in soil, the concentrations in groundwater are expected to be low. This is supported by water modelling which indicates that groundwater levels are low. Based on its low volatility, flonicamid residues are not expected in the air.

Flonicamid does not present a risk to wild mammals, birds, freshwater or marine invertebrates and fish, amphibians, algae, and aquatic plants. However, flonicamid does potentially affect terrestrial plants and predators and parasites. Therefore, to protect from the effects resulting from spray drift to non-target terrestrial plants, a ground buffer zone of one metre is required. Hazard based label statements for toxicity are required for predators and parasites, and terrestrial plants.

Value Considerations

What Is the Value of Beleaf 50SG Insecticide?

Beleaf 50SG Insecticide controls aphids on a wide variety of agricultural crops.

The active ingredient in Beleaf 50SG Insecticide will be useful in resistance management as it has a different mode of action compared to the currently registered pest control products in the same crops. It can also be used as an alternative to older chemistries registered for the same uses, such as organochlorines, organophosphates and carbamates.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Beleaf 50SG Insecticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

A 12-hour restricted-entry interval (REI) for agricultural products encompasses most post-application tasks; however, longer REIs are necessary for some tasks on several crops, including hops, pome fruits and stone fruits. For hops, a 31-day REI is required for stripping, training and hand harvest activities. For pome and stone fruits, a 2-day REI is required for thinning activities.

Environment

Beleaf 50SC Insecticide can not be sprayed within one metre of susceptible non-target plant species. Label statements for toxicity are required for predators and parasites, and terrestrial plants.

Other Information

1. The relevant test data on which the decision is based (as referenced in PRD2010-25 *Flonicamid*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.